



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 25, 2015

Ms. Leslie Garcia  
Regulatory Consultant  
Technology Sciences Group, Inc.  
c/o Star Business Products, Inc.  
115 Freen View Dr.  
Madison, MS 39110

**Subject:** Label Amendment – The registrant was requesting to adjust the dosing volume of the product. Additionally, the dog spot-on mitigation language had not been added to the label nor had the 2011 spot-on mitigation letter. Therefore, the label includes the revised dosing volume and the mitigation language.  
Product Name: Freedom® 45 Spot On for Dogs  
EPA Registration Number: 75257-1  
Application Date: April 19, 2012 and October 31, 2014  
Decision Number: 471114 and 496996

Dear Ms. Garcia:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(B), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. This registration is time-limited and expires two years from the date of this letter.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred. (mm/dd/yyyy)
  - State in which the incident occurred. (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)

- Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
- All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
  - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - A summary table showing the number of dogs incidents for each severity code for each pet weight range on the product label, as applicable.
  - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
  - Table showing number of incidents for each dog breed, where provided.
  - Table showing number of incidents in dogs for each clinical sign.
  - Table showing number of incidents in dogs for each organ system.
  - Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the

product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

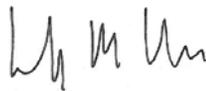
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 03/09/2009
- Alternate CSF 1 dated 03/09/2009

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Jennifer Gaines by phone at (703) 305-5967 or via email at [gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov).

Sincerely,



Jennifer Urbanski, PhD, Product Manager 4  
Invertebrate and Vertebrate Branch 1 (IVB1)  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

(Front panel - Carton Label)  
(Picture of dog that is appropriate for each weight range)

# FREEDOM 45 SPOT ON FOR DOGS

[reviewer note: Font size for word "Dog" in product name will be at least 75% the height of the largest letter in the primary brand name]

**FOR USE ONLY ON DOGS OR PUPPIES 12 WEEKS OF AGE OR OLDER, WEIGHING [5-10 LBS.] [11-32 LBS.] [33-66 LBS.] [MORE THAN 66 LBS.]**



### DO NOT USE ON CATS – MAY BE FATAL

Keep cats away from treated dogs for 24 hours.

If applied to or ingested by a cat, contact your veterinarian immediately.

[reviewer note: 1.5 x 1.5 cm icon and statement will be placed on the lower right hand corner of front panel]

- [Kills, repels and prevents re-infestation of fleas for up to 5 weeks]
- [Kills, repels and prevents re-infestation of fleas for up to 4 weeks]
- [Kills, repels and prevents re-infestation of ticks for up to 6 weeks]
- [Kills, repels and prevents re-infestation of ticks for up to 4 weeks]
- [Kills, repels mosquitoes, lice and mites on dogs for up to 4 weeks]
- [Additional market claims – see last page for list of options]

<b>ACCEPTED</b>
<b>06/25/2015</b>
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. <b>75257-1</b>

#### ACTIVE INGREDIENT

Permethrin\* (CAS# 52645-53-1) ..... 45.00%

OTHER INGREDIENTS ..... 55.00%

TOTAL ..... 100.00%

\* Cis/trans ratio: max 55% [±] cis and min 45% [±] trans

## KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS  
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Star Business Products  
115 Green View Drive  
Madison, MS 39110

EPA Registration No. 75257-1  
EPA Establishment No. 75844-CA-02

Package contains a one [1], two [2], three [3], four [4], six [6], eight [8], twelve [12] month supply (as applicable)

#### Net Contents

2 [3, 4, 6, 8, 12] x 0.xx fl.oz. (xx ml) applicators

(Side/Back panel - Carton label)

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMAN AND DOMESTIC ANIMALS  
CAUTION**

**Hazards to Humans:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before re-use.

**Hazards to Domestic Animals: For external use on dogs only. Do not use on cats or animals other than dogs. Do not treat (use on) dogs or puppies less than 12 weeks of age, weighing less than 5 lbs.** Consult a veterinarian before using this product on debilitated, aged, or medicated animals, pregnant or nursing pups. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product on pets. If signs of sensitivity occur, discontinue use, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site and lethargy.

**DO NOT USE ON CATS: May be toxic or potentially fatal if applied to or ingested by cats.** Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

**FIRST AID**

**IF SWALLOWED:**

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

**IF ON SKIN OR CLOTHING:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

**HOTLINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call 1-303-389-1883 twenty four [24] hours per day, seven [7] days per week.

**ENVIRONMENTAL HAZARDS**

This product is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. Do not allow treated dogs to go swimming for 12 hours following treatment.

**CHEMICAL HAZARDS**

Do not use or store near heat or open flame.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### USE RESTRICTIONS

- **DO NOT USE ON CATS OR KITTENS. Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.**
- Do not apply this product to puppies less than 12 weeks of age, weighing less than 5 lbs.

Ready to use, no dilution necessary. Apply this product only as specified on this label. Do not contaminate food or feedstuff.

[reviewer note: optional graphic /photographs/images to illustrate instructions see example]



- Hold tube in upright position pointing away from user's and dog's face and body. Break off tip or cut with scissors.
- Apply FREEDOM 45 SPOT ON FOR DOGS [this product] by gently squeezing the applicator. Part dog's hair between shoulder blades.
- Apply specified amount of solution to the skin on the dog's back between the shoulder blades. For large and extra-large dogs, application of the solution to the skin directly in front of the base of the dog's tails is also required. SEE DOSING GUIDELINES BELOW.

Packages for [puppy/toy/miniature] dogs weighing 5-10 lbs.

Apply 0.75 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

Package for [small] dogs weighing 11-32 lbs.

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

Package for [large] dogs weighing 33-66 lbs.

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 1.50 ml to the skin directly in front of the base on the dog's tail

Package for [extra (ex-) large (XL) dogs weighing more than 66 lbs.

Apply 3.0 ml of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 3.0 ml to the skin directly in front of the base on the dog's tail. Do not double-dose dogs larger than 66 lbs.

Multi package

For [puppy/toy/miniature] dogs weighing 5-10 lbs.

Apply 0.75 ml of FREEDOM 45 SPOT ON FOR DOGS (1 tube) to the skin of the dog's back between the shoulder blades

For [small] dogs weighing 11-32 lbs.

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades.

For [large] dogs weighing 33-66 lbs.

Apply 1.50 ml of FREEDOM 45 SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades and 1.50 ml (another 2 tubes) to the skin directly in front of the base on the dog's tail

For [extra (ex-) large (XL) dogs weighing more than 66 lbs.

Apply 3.0 ml of FREEDOM 45 SPOT ON FOR DOGS (4 tubes) to the skin of the dog's back between the shoulder blades and 3.0 ml (another 4 tubes) to the skin directly in front of the base on the dog's tail. Do not double-dose dogs larger than 66 lbs.

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian.

DO NOT USE ON CATS – MAY BE FATAL or Cat/Slash Icon/Graphic (representative graphic)  
[reviewer note:1.5 x 1.5 cm icon and statement will be placed on the lower right hand corner of front panel]



#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry (preferable locked) place, away from heat or open flame, in an area that is inaccessible to children and animals.

**Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Handling (tubes):** If empty: Do not reuse or refill the tube. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### WARRANTY

Star Business Products warrants that this product conforms to the chemical description on the label. Star Business Products neither makes nor authorizes any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express or implied concerning this material. To the extent consistent with applicable law Star Business Products' maximum liability for breach of this warranty shall not exceed the purchase price of this product. To the extent consistent with the applicable law Buyer and user acknowledge and assume all risk and liabilities resulting from the handling, storage and use of this product which extend beyond the use of the product under normal conditions and in accord with statements made on the label.

Lot/Batch # \_\_\_\_\_

[Applicator Tube]

FREEDOM 45% SPOT ON FOR DOGS  
PERMETHRIN INSECTICIDE 45%

KEEP OUT OF REACH OF CHILDREN

DO NOT USE ON CATS – MAY BE FATAL or Cat/Slash Icon/Graphic (representative graphic)

EPA Reg. No. 75257-1

Read entire label before each use.

[puppy/small dog/large dog/ ex-large (XL) dog]



#### ALTERNATIVE MARKETING CLAIMS

- Kills fleas, ticks, mosquitoes, lice, and mites
- Kills five [5] pests: fleas, ticks, mosquitoes, lice, and mites on dogs
- Kills five [5] different canine pests: fleas, ticks, mosquitoes, lice, and mites
- Kills and repels mosquitos